IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Clark R. Baker, Jr.	§	Confirmation No.:	1106
Serial No.: 10/796,584	§	Group Art Unit:	3737
Filed: March 8, 2004	§	Examiner:	Ramirez, John Fernando
For: Method and Apparatus for Optical Detection of Mixed Venous and Arterial Blood Pulsation in Tissue	§	Atty. Docket:	TYHC:0149/FLE/COH P0409R

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February 4, 2008	/W. Allen Powell/
Date	W. Allen Powell

APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 41.31 AND 41.37

This Appeal Brief is being filed in furtherance of the Notice of Appeal mailed on October 22, 2007, and received by the Patent Office on October 24, 2007. Appellant filed a Pre-Appeal Brief Request for Review with the Notice of Appeal. In a Notice of Panel Decision from Pre-Appeal Brief Review mailed January 4, 2008, the Office reset the time period for filing an appeal brief to one month from the mailing date of the decision, i.e., February 4, 2008. Consequently, Appellant respectfully submits that the present Appeal Brief is timely.

The Commissioner is authorized to charge the requisite filing fee of $510.00, and any additional fees that may be required, to the credit card listed on the attached PTO-2038. However, if the PTO-2038 is missing, if the amount listed thereon is insufficient, or if the amount is unable to be charged to the credit card for any other reason, the Commissioner is authorized to charge Deposit Account No. 06-1315; Order No. TYHC:0149/FLE (P0409R).

1. REAL PARTY IN INTEREST

The real party in interest is Covidien, the Assignee of the above-referenced application by virtue of the Assignment to Nellcor Puritan Bennett LLC, a subsidiary of Covidien, recorded at reel 015602, frame 0416, and dated July 26, 2004. Accordingly, Covidien, as the parent company of the Assignee of the above-referenced application, will be directly affected by the Board's decision in the pending appeal.

2. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any other appeals or interferences related to this Appeal. The undersigned is Appellant's legal representative in this Appeal.

3. STATUS OF CLAIMS

Claims 1-27 are currently pending. Claims 1-22 are currently under final rejection and, thus, are the subject of this Appeal. Claims 23-27 are withdrawn.

4. STATUS OF AMENDMENTS

The claim amendments submitted in the Amendment and Response to Office Action mailed on November 5, 2005, have been entered, and no subsequent amendments were submitted. Therefore, the present application is not subject to any pending amendments.

5. SUMMARY OF CLAIMED SUBJECT MATTER

This Appeal Brief addresses independent claims 1 and 13 and the claims depending therefrom. Below, Appellant explains each of the independent claims by identifying specific embodiments in the specification. While these embodiments exemplify the subject matter of the appealed claims, they do not necessarily define the claims' scope. Thus, these claims should not be construed as limited to the following embodiments by virtue of this explanation.

The present invention relates generally to the field of pulse oximetry, and in particular to the processing of signals generated by a pulse oximeter to detect the presence of a phenomenon known as "venous pulsation." Specification, page 1, lines 5-6 and 23-25. In pulse oximetry, venous pulsation may interfere with the calculation of various physiological parameters, such as oxygen saturation or pulse rate. Specification, page 9, lines 23-28. Venous pulsation is generally believed to be caused by venous blood backing up and pooling due to a lack of sufficient valves in the vascular anatomy. Specification, page 9, lines 18-22. Venous pulsation is more common in certain areas of the body where there are fewer valves, such as the head or forehead. *Id.* In addition, a patient's medical condition may increase the likelihood that venous pulsation will occur. *Id.* Typically, caregivers are instructed to secure sensors to patients tightly enough to overcome any venous pulsation, but it is not easy to determine whether any particular sensor has been secured properly. Specification, page 9, lines 31-34. Venous pulsation is distinguishable from motion artifact, in part, because it may occur absent patient motion. *See* Specification, page 9, lines 29-30. Accordingly, the present application is directed to detecting the presence of venous pulsation so that a caregiver may be notified and take measures to preclude the presence of further venous pulsations (e.g., by tightening the sensor on the patient).

With regard to the aspect of the invention set forth in independent claim 1, discussions of the recited features of claim 1 can be found at least in the below cited locations of the specification and drawings. By way of example, a method of detecting the presence of mixed venous and arterial blood pulsation in tissue includes receiving first and second electromagnetic radiation signals (*see, e.g.,* Specification, page 3, line 33 – page 4, line 1; FIG. 1, detector 114) from a blood perfused tissue portion (*see, e.g., id.*; FIG. 1, patient 112) corresponding to infrared and red wavelengths of light (*see, e.g.,* Specification, page 3, lines 11-14; page 5, lines 20-22; FIG. 1, light source 110); obtaining a measure of a phase difference between the first and second electromagnetic radiation signals (*see, e.g.,* Specification, page 10, line 11 – page 12, line 17; page 12, line 29 – page 13, line 2; FIGS. 3A and 3B); comparing the measure with a threshold value to form a comparison (*see, e.g.,* Specification, page 12, lines 19-28); detecting the presence or absence of venous pulsation using the comparison (*see, e.g.,* Specification, page 12, lines 19-

20; page 13, lines 3-9; FIG. 4); and indicating the presence of venous pulsation to a caregiver if venous pulsation is present (*see, e.g.,* Specification, page 13, lines 13-21).

With regard to the aspect of the invention set forth in independent claim 13, discussions of the recited features of claim 13 can be found at least in the below cited locations of the specification and drawings. By way of example, a device for detecting the presence of mixed venous and arterial blood pulsation in tissue includes means for receiving first and second electromagnetic radiation signals (*see, e.g.,* Specification, page 3, line 33 – page 4, line 1; FIG. 1, detector 114) from a blood perfused tissue portion (*see, e.g., id.*; FIG. 1, patient 112) corresponding to infrared and red wavelengths of light (*see, e.g.,* Specification, page 3, lines 11-14; page 5, lines 20-22; FIG. 1, light source 110); means for obtaining a measure of a phase difference between the first and second electromagnetic radiation signals (*see, e.g.,* Specification, page 10, line 11 – page 12, line 17; page 12, line 29 – page 13, line 2; FIGS. 3A and 3B); means for comparing the measure with a threshold value to form a comparison (*see, e.g.,* Specification, page 12, lines 19-28); means for detecting the presence or absence of venous pulsation using the comparison (*see, e.g.,* Specification, page 12, lines 19-20; page 13, lines 3-9; FIG. 4); and means for indicating the presence of venous pulsation to a caregiver when venous pulsation is present (*see, e.g.,* Specification, page 13, lines 13-21).

A benefit of the invention, as recited in these claims, is the ability to detect the presence of venous pulsation in a pulse oximetry signal and detect a caregiver of the presence of venous pulsation when detected. This is a clear difference and distinction from the prior art, as discussed below.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. First Ground of Rejection for Review on Appeal

Appellant respectfully urges the Board to review and reverse the Examiner's first ground of rejection in which the Examiner rejected claims 1-22 under 35 U.S.C. § 112, second

paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention.

B. Second Ground of Rejection for Review on Appeal

Appellant respectfully urges the Board to review and reverse the Examiner's second ground of rejection in which the Examiner rejected claims 1-4, 6-16, and 18-22 under 35 U.S.C. § 103(a) as being unpatentable over Diab et al. (U.S. Publication No. 2003/0036689) in view of Swedlow et al. (U.S. Patent No. 5,662,106).

7. ARGUMENT

As discussed in detail below, the Examiner has improperly rejected the pending claims. Further, the Examiner has misapplied long-standing and binding legal precedents and principles in rejecting the claims under 35 U.S.C. §§ 112 and 103. Accordingly, Appellant respectfully requests full and favorable consideration by the Board, as Appellant strongly believes that claims 1-22 are currently in condition for allowance.

A. First Ground of Rejection

The Examiner rejected claims 1-22 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention. Appellant respectfully traverses this rejection.

Legal Precedent

The Examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. § 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. *See* M.P.E.P. § 2173.02. Although the Examiner may take exception to the terms used in the claims, the patentee may be his own lexicographer. *Ellipse Corp. v. Ford Motor Co.*, 171 U.S.P.Q. 513 (7th Cir. 1971), *aff'd.* 613 F.2d 775 (7th Cir. 1979), *cert. denied*, 446 U.S. 939 (1980). Applicants may use functional language, alternative expressions, negative

limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. *See* M.P.E.P. §§ 2173.01 and 2173.05; *In re Swinehart*, 439 F.2d 10, 160 U.S.P.Q. 226, (CCPA 1971). The Examiner is also reminded not to equate breadth of a claim with indefiniteness. *In re Miller*, 441 F.2d 689, 169 U.S.P.Q 597 (CCPA 1971).

The essential inquiry pertaining to the definiteness requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. *See* M.P.E.P. § 2173.02. As set forth in Section 2173 of the Manual of Patent Examining Procedure, definiteness of claim language must be analyzed, not in a vacuum, but in light of:

> (A) The content of the particular application disclosure;
> (B) The teachings of the prior art; and
> (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. *See Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 U.S.P.Q.2d 1279, 1283 (Fed. Cir. 2000). Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite. *See Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 U.S.P.Q.2d 1081, 1089 (Fed. Cir. 2004). Accordingly, a claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible. *See Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 U.S.P.Q.2d 1996, 1999-2000 (Fed. Cir. 2004).

Deficiencies of the Rejection of Claims 1-22 under 35 U.S.C. § 112, Second Paragraph

In rejecting independent claims 1 and 13, the Examiner stated:

> In claims 1 and 13, it is unclear as to how one calculates and measures the phase difference between the two electromagnetic radiation signals. Therefore, it is also unclear as to how one detects the presence or absence of venous pulsation by comparing the measure of the phase difference with a threshold value.

Final Office Action, page 3.

Embodiments of phase difference calculations are clearly described in the present application. For example, the phase difference may be calculated by determining the openness of a Lissajous plot of a red waveform versus an infrared waveform. *See, e.g.,* Specification, page 10 – page 12, line 17. Indeed, specific exemplary algorithms are provided to enable one skilled in the art to calculate a phase difference metric. *See, e.g.,* Specification, page 11, lines 18-24; page 12, lines 1-17. Further techniques for calculating the phase difference may include quantifying the cross-correlation function of the two waveforms as a function of a delay interval between them or subtracting the phases of the waveforms at a given frequency. *See, e.g.,* Specification, page 12, line 29 – page 13, line 2. Additionally, detection of the presence of venous pulsation is clearly described in the present application. For example, venous pulsation may be detected by comparing the phase difference value to a threshold value. *See, e.g.,* Specification, page 12, lines 19-28; page 13, lines 3-21; *see also* FIG. 4.

In view of these multiple exemplary techniques for measuring the phase difference between first and second electromagnetic signals and for comparing the phase difference measurement to a threshold to detect the presence of venous pulsation described in the present application, Appellant respectfully asserts that independent claims 1 and 13 clearly are not indefinite. In addition, the rejection of dependent claims 2-12 and 14-22 was based solely on their dependence from independent claims 1 and 13, respectively. Accordingly, Appellant respectfully asserts that the Examiner's rejections of independent claims 1 and 13, and the claims depending therefrom, under 35 U.S.C. § 112, second paragraph, are in error. Indeed, the Examiner clearly has not followed the guidelines set forth in Section 2173 of the M.P.E.P. in analyzing the definiteness of the present claim language. Appellant therefore respectfully

requests the Board overturn the rejection of claims 1-22 under 35 U.S.C. § 112, second paragraph.

B. Second Ground of Rejection

The Examiner rejected claims 1-4, 6-16, and 18-22 under 35 U.S.C. § 103(a) as being unpatentable over Diab et al. (U.S. Publication No. 2003/0036689) in view of Swedlow et al. (U.S. Patent No. 5,662,106). Appellant respectfully traverses this rejection.

Legal Precedent

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). In addressing obviousness determinations under 35 U.S.C. § 103, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (April 30, 2007), reaffirmed many of its precedents relating to obviousness including its holding in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). In *Graham*, the Court set out an objective analysis for applying the statutory language of §103:

> Under §103, the scope and content of the prior art are to be determined, differences between the prior art and the claims at issue are to be ascertained, and the level of ordinary skill in the pertinent art are to be resolved. Against this background the obviousness or non-obviousness of the subject matter is to be determined. Such secondary considerations as commercial success, long-felt but unresolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

KSR, *slip op.* at 2 (citing *Graham*, 383 U.S. at 17-18).

In addition, in making an obviousness determination, the pending claims must be given an interpretation that is reasonable and consistent with the specification. *See In re Prater*, 415 F.2d 1393, 1404-05, 162 U.S.P.Q. 541, 550-51 (C.C.P.A. 1969). Interpretation of the claims must also be consistent with the interpretation that one of ordinary skill in the art would reach. *See In re Cortright*, 165 F.3d 1353, 1359, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999); M.P.E.P. § 2111. "The inquiry into how a person of ordinary skill in the art understands a claim term

provides an objective baseline from which to begin claim interpretation." *See Collegenet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 75 U.S.P.Q.2d 1733, 1738 (Fed. Cir. 2005) (quoting *Phillips v. AWH Corp.*, 75 U.S.P.Q.2d 1321, 1326). The Federal Circuit has made clear that derivation of a claim term must be based on "usage in the ordinary and accustomed meaning of the words amongst artisans of ordinary skill in the relevant art." *See id.*

Furthermore, where the Examiner takes Official Notice and relies on facts outside the record to support a rejection, such facts must be of a "notorious character" and "capable of such instant and unquestionable demonstration as to defy dispute." M.P.E.P. § 2144.03 (8TH REV., SEPTEMBER 2007) (emphasis added). The use of Official Notice is improper on a legal basis where the Official Notice is a broad sweeping statement as to all features of all pending claims. *See id.* Specifically, in Section 2144.03, the Manual of Patenting Examining Procedure specifically states:

> In certain circumstances where appropriate, an examiner may take official notice of facts not in the record or rely on "common knowledge" in making a rejection, however such rejections should be judiciously applied.
>
> ...
>
> As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)). ... Furthermore, it might not be unreasonable for the examiner in a first Office action to take official notice of facts by asserting that certain limitations in a dependent claim are old and well known expedients in the art without the support of documentary evidence provided the facts so noticed are of notorious character and serve only to "fill in the gaps" which might exist in the evidentiary showing made by the examiner to support a particular ground of rejection. *In re Zurko*, 258 F.3d 1379, 1385, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001); *Ahlert*, 424 F.2d at 1092, 165 USPQ at 421.
>
> It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. For example,

> assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at 420-21.
>
> ...
>
> It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 ("[T]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.").
>
> ...
>
> The examiner must provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge. See *Soli*, 317 F.2d at 946, 37 USPQ at 801; *Chevenard*, 139 F.2d at 713, 60 USPQ at 241.
>
> ...
>
> If applicant adequately traverses the examiner's assertion of official notice, the examiner must provide documentary evidence in the next Office action if the rejection is to be maintained. See 37 CFR 1.104(c)(2).

Accordingly, the Examiner's use of Official Notice to obviate technical claims must be supported by documentary evidence. Further, the use of Official Notice is improper where the scope of the Official Notice is far beyond an insubstantial gap in the cited reference.

Deficiencies of the Rejection of Independent Claims 1 and 13 under 35 U.S.C. § 103(a)

As noted above, the Examiner rejected claims 1-4, 6-16, and 18-22 under 35 U.S.C. § 103(a) as being unpatentable over Diab in view of Swedlow. The Examiner alleged that features of independent claims 1 and 13 are disclosed in the prior art. Appellant respectfully disagrees. Independent claim 1 recites:

> 1. A method of detecting the presence of mixed venous and arterial blood pulsation in tissue, comprising:
>
> receiving first and second electromagnetic radiation signals from a blood perfused tissue portion corresponding to infrared and red wavelengths of light;

obtaining a measure of a phase difference between the first and second electromagnetic radiation signals;

comparing the measure with a threshold value to form a comparison;

detecting the presence or absence of venous pulsation using the comparison; and

indicating the presence of venous pulsation to a caregiver if venous pulsation is present.

Similarly, independent claim 13 recites:

13. A device for detecting the presence of mixed venous and arterial blood pulsation in tissue, comprising:

means for receiving first and second electromagnetic radiation signals from a blood perfused tissue portion corresponding to infrared and red wavelengths of light;

means for obtaining a measure of a phase difference between the first and second electromagnetic radiation signals;

means for comparing the measure with a threshold value to form a comparison;

means for detecting the presence or absence of venous pulsation using the comparison; and

means for indicating the presence of venous pulsation to a caregiver when venous pulsation is present.

In rejecting independent claims 1 and 13, the Examiner stated:

With respect to claims 1-4, 6-16, 18-22, the Diab et al. patent teaches a system for detecting the presence of mixed venous and arterial blood pulsation in tissue, (abstract, paragraph 0019), obtaining a measure of a phase difference between said first and second electromagnetic radiation signals (paragraphs 0389-0391, fig. 25B, elements 694, 692, 690), comparing said measure with a threshold value to form a comparison (paragraph 0387, fig. 25B, elements 660, 662, 696); and detecting the presence or absence of venous pulsation using said comparison (paragraphs 0019, 0368). (NOTE: it is well known in the art that the primary cause of noise in transmissive pulse oximetry measurements is motion artifact caused by the movement of venous blood in the finger).

Diab et al. do not disclose indicating the presence of venous pulsation to a caregiver if venous pulsation is present. However, the Swedlow et al. patent teaches an indication of the presence of venous pulsation to a caregiver if venous pulsation is

> present (see abstract, fig. 1, element 30, and figure 4, col. 5, line 64 – col. 6, line 34).
>
> It would have been obvious for a person of ordinary skill in the art, to modify the system disclosed by Diab et al., with the above discussed enhancements because such modification would provide a more accurate blood oxygen and pulse readings.

Final Office Action, pages 3-4. Furthermore, in response to Appellant's previous arguments regarding the improper rejection of claims 1 and 13, the Examiner stated:

> Applicant alleges on page 10 of the remarks, that the Swedlow reference does not disclose detection of the venous pulsation, much less an indication of its presence. The examiner of record respectfully disagrees with applicant's assertions. It is commonly understood in pulse oximetry that the detected physiologic signals in response to both red and infrared light consist of desired signal portions as well as undesired signal portions. The desired signal portions are proportional to one another through the arterial optical density ratio. The resultant is a reference signal that contains only noise portions. Considering the finger for example, the venous blood in the vascular bed will be easily deformed during motion. In addition, the venous blood is a strong absorber of light. Hence, it can represent a significant contributor to the total optical density during motion episodes. During routine patient motions (shievering [*sic*], waving, tapping, etc.), the resulting noise can be quite substantial and can easily overwhelm a conventional ratio based oximetry system. Having identified the venous blood as a significant contributor to noise during motion.

Final Office Action, page 2.

The Examiner's interpretations of the Diab and Swedlow references are clearly erroneous. Despite the Examiner's assertions to the contrary, the Diab reference does not disclose detecting the presence of venous pulsation. Regarding the passages cited by the Examiner, the Diab reference discloses that a plethysmographic wave contains primary and secondary portions. *See* Diab, ¶ [0019]. The secondary portion is noise and may include several parameters, including patient movement, venous blood contribution to attenuation of energy as it passes through the body, and respiration. *See id.* A parameter "n" utilized in algorithms

disclosed in the Diab reference represents noise, including "information on the venous blood, as well as motion artifacts and other noise." Diab, ¶ [0368] (emphasis added). The sources of noise in the secondary portion of the plethysmographic wave are not sorted or specifically identified. Diab does not disclose a method or means for detecting venous pulsation but rather discloses that a portion of the plethysmographic wave may include a hodgepodge of various noise signals. That is, the secondary portion of the plethysmographic wave may or may not contain noise due to venous pulsation.

Regarding the phase difference measurement recited in claims 1 and 13, the Diab reference discusses a phase difference measurement between red and IR signals; however, this measurement is not obtained to form a comparison with a threshold to detect the presence of venous pulsation. *See* Diab, ¶¶ [0389]-[0393]. Rather, according to the Diab reference, if the phase difference between a red and IR point is low enough, the points are used to calculate a saturation value. *See* Diab, ¶¶ [0393]-[0394]. That is, the Diab reference discloses calculation of arterial and venous saturation. *See* Diab, ¶ [0395]. Again, Appellant finds no discussion in the Diab reference regarding detecting the presence or absence of a venous pulsation. The Diab reference also does not disclose that an indication of venous pulsation is provided to a caregiver for any reason. Indeed, the Examiner stated, "Diab et al. do not disclose indicating the presence of venous pulsation to a caregiver if venous pulsation is present." Final Office Action, page 4.

Furthermore, the Swedlow reference does not cure the deficiencies of the Diab reference. The Swedlow reference discloses modification of an alarm condition when motion is detected. *See* Swedlow, Abstract. Nothing in the Swedlow reference discloses detection of venous pulsation, much less an indication of its presence. Rather, the Swedlow reference merely discloses a pulse oximeter that detects motion artifacts. *See* Swedlow, col. 1, lines 10-13; col. 2, lines 52-53; col. 5, line 64 – col. 6, line 14. Specifically, the Swedlow reference relates to detection of a motion artifact, "such as by the detector moving away from the skin temporarily." Swedlow, col. 2, lines 14-15.

To overcome the deficiencies of the Diab and Swedlow references, the Examiner stated that "it is well known in the art that the primary cause of noise in transmissive pulse oximetry

measurements is motion artifact caused by the movement of venous blood in the finger." Final Office Action, page 4. First, this statement is plainly incorrect. In addition, in making this statement, the Examiner has essentially taken Official Notice of facts outside of the record that the Examiner apparently believes are capable of demonstration as being "well-known" in the art. Specifically, the Examiner has erroneously equated motion artifacts to venous pulsation in pulse oximetry.

Venous pulsation and motion artifact are different phenomena. Accordingly, this is clear error by the Examiner. Interference with pulse oximetry readings may be caused by a wide variety of sources, such as, but not limited to, venous pulsation, physical movement of the patient, dysfunctional hemoglobin, low perfusion, intermittent pulsatility or arrhythmia, electromagnetic interference, ventilator-induced pressure changes, or ambient light. Each of these sources of interference is caused by different phenomena and may be handled differently. For example, as discussed above, and as addressed in the present application, venous pulsation is a phenomenon caused by a patient's vascular anatomy and aggravated by some medical conditions or procedures. *See* Specification, page 9, lines 18-22. A motion artifact, on the other hand, is due to movement of the sensor with respect to the patient. *See, e.g.,* Swedlow, col. 2, lines 11-15. For example, the secondary portion of the plethysmographic wave disclosed in the Diab reference includes signals from respiration, patient movement, and venous blood contribution to attenuation of energy as it passes through the body. *See* Diab, ¶ [0019]. Appellant does not dispute that motion artifacts can create problems in measuring physiological parameters, such as oxygen saturation. However, this is not the issue addressed by the present claims. On the contrary, the present claims relate to detection and notification of venous pulsation, which is a different phenomenon from motion artifact.

In addition to the factual deficiencies of the Examiner's Office Notice, Appellant submits that the Examiner's use of Official Notice is improper on a legal basis because the Official Notice is a broad sweeping statement as to all features of all pending claims and is far beyond an insubstantial gap in the cited reference. In the Response to Office Action mailed on February 12, 2007, Appellant traversed the Examiner's use of Official Notice in accordance with M.P.E.P. §

2144.03 and requested that the Examiner produce evidence in support of the Examiner's position. Specifically, Appellant requested evidence so support the Examiner's position that "the primary cause of noise in transmissive pulse oximetry measurements is motion artifact caused by the movement of venous blood in the finger." *See* Response to Office Action mailed February 12, 2007, pages 10-11. In the Final Office Action, the Examiner failed to produce documentary evidence from a reference work recognized as standard in the field of pulse oximetry. *See* M.P.E.P. § 2144.03.

For at least the reasons set forth above, the Examiner has failed to establish a *prima facie* case of obviousness in rejecting claims 1-22. The cited references do not disclose detection of venous pulsation as alleged by the Examiner. Furthermore, the Examiner has erroneously equated motion artifact with venous pulsation and has provided no evidence that such an equivalent is "well-known" in the art. Accordingly, Appellant respectfully asserts that the Examiner's rejections under 35 U.S.C. § 103(a) are in error. Appellant therefore respectfully requests the Board overturn the rejection of claims 1-22 under 35 U.S.C. § 103.

Deficiencies of the Rejection of Dependent Claims under 35 U.S.C. § 103(a)

As noted above, in the Final Office Action, the Examiner rejected claims 1-4, 6-16, and 18-22 under 35 U.S.C. § 103(a) as being obvious over the Diab reference in view of the Swedlow reference. Appellant submits that the claims depending from independent claims 1 and 13 are patentable at least based on their dependencies from allowable based claims. In addition, the dependent claims recite unique features not disclosed in either the Diab reference or the Swedlow reference. Accordingly, Appellant respectfully submits that the Examiner's rejection of dependent claims 2-4, 6-12, 14-16, and 18-22 is in error.

First, Appellant notes that the Examiner did not address elements recited in the dependent claims in the Final Office Action, and therefore has failed to make a *prima facie* case of obviousness for any of the dependent claims. In the rejection of claims 1-4, 6-16, and 18-22, the Examiner referred only to the independent claims. Final Office Action, pages 3-4. Furthermore, although the Examiner detailed rejections of the dependent claims in the Office Action mailed on

November 25, 2005, these rejections were withdrawn in view of the Appellant's persuasive arguments. Office Action mailed on July 14, 2006, page 2.

After withdrawing the rejections set forth in the Office Action mailed on November 25, 2005, the Examiner merely stated:

> Diab et al., teaches all the limitations of the claimed subject matter except for mentioning specifically the steps of indicating the presence of venous pulsation to a caregiver, obtaining a measure of a phase difference comprises obtaining a measure of the openness of an ellipse on a Lissajous plot formed by comparing the first electromagnetic radiation signal against the second electromagnetic radiation signal.

Office Action mailed on July 14, 2006, page 3. These elements refer to limitations recited in independent claims 1 and 13 and in dependent claims 5 and 17. The Examiner cited Mortz (U.S. Patent No. 6,987,994) for disclosing the limitation of "indicating the presence of venous pulsation to a caregiver if venous pulsation is present" as recited in claim 1 and similarly recited in claim 13. Office Action mailed on July 14, 2006, page 3. The Examiner further cited Chin et al. (U.S. Patent No. 6,018,673) for disclosing the limitation of "obtaining a measure of the openness of an ellipse on a Lissajous plot formed by comparing the first electromagnetic radiation signal against the second electromagnetic radiation signal" as recited in claim 5 and similarly recited in claim 17. Office Action mailed on July 14, 2006, pages 3-4. The Examiner did not assert specific rejections against any of the remaining dependent claims.

In the Office Action mailed on February 17, 2007, the Examiner stated that the Appellant's arguments in response to the previous Office Action mailed on July 14, 2006, were persuasive. The Examiner withdrew the rejection of dependent claims 5 and 17 and indicated that these claims contain allowable subject matter. Office Action mailed on February 17, 2007, page 3. The Examiner also set forth a new obviousness rejection of claims 1-4, 6-16, and 18-22 based on the Diab and Swedlow references. However, in this rejection the Examiner merely cited limitations of the independent claims 1 and 13 which were allegedly disclosed in the prior art. The limitations set forth in dependent claims 2-4, 6-12, 14-16, and 18-22 were not addressed

in this Office Action or in the Final Office Action which followed. *See* Office Action mailed on February 17, 2007; Final Office Action mailed on August 22, 2007. Accordingly, Appellant respectfully requests the Board overturn the rejection of dependent claims 2-4, 6-12, 14-16, and 18-22 under 35 U.S.C. § 103.

Regardless of the Examiner's improper legal basis for rejecting dependent claims 2-4, 6-12, 14-16, and 18-22, these claims clearly recite elements not disclosed in the Diab and/or Swedlow references. For example, dependent claim 2 recites "filtering the first and second electromagnetic radiation signals before the obtaining the measure, to pass portions of the first and second electromagnetic radiation signals having frequencies at or near the pulse rate or harmonics of the pulse rate of the blood perfused tissue." (Emphasis added). Dependent claim 14 contains similar language. The Examiner, in a withdrawn rejection, alleged that elements 645 and 647 of the Diab reference disclose the recited limitation. Office Action mailed on November 25, 2005, page 3. However, Diab does not disclose that the infrared and red high-pass filter modules 645, 647 pass portions of the radiation signals with specific frequencies related to the patient's pulse rate as recited in claims 2 and 14.

Dependent claim 3 recites "obtaining a measure of a persistent phase difference between the first and second electromagnetic radiation signals." (Emphasis added). Dependent claim 15 recites similar language. Although the Diab reference discloses a phase difference module 694, as cited by the Examiner, there is no indication that the phase difference module 694 measures a persistent phase difference as recited in claims 3 and 15. *See* Office Action mailed on November 25, 2005, page 3; *see also* Diab, ¶ [0383].

Dependent claim 4 recites "integrating the measure of a phase difference over a time period," and dependent claim 16 recites similar language. Despite the Examiner's assertions to the contrary, nothing in the Diab reference discloses integrating the phase difference calculated in the phase difference module 694. *See* Office Action mailed on November 25, 2005, page 3; *see also* Diab, ¶ [0389].

Dependent claim 6 recites "analyzing a cross-correlation function of the first and second electromagnetic radiation signals, as a function of a delay interval between them," and dependent claim 18 recites similar language. The Diab reference states that a cross-correlation output "indicates a cross-correlation between the red and infrared signals." Diab, ¶ [0270]. However, there is no indication that this cross-correlation function is analyzed as a function of a delay interval between the radiation signals as recited in claims 6 and 18.

Dependent claim 8 recites "taking the complex conjugate of the first and second electromagnetic radiation signals, and dividing the complex conjugate by the product of the magnitudes of the first and second electromagnetic radiation signals." Dependent claim 20 recites similar language. The Examiner cited the complex fast Fourier transform modules 652, 654 and magnitude modules 656, 658 of Diab for disclosing the recited limitations. Office Action mailed on November 25, 2005, page 3. However, the FFT modules 652, 654 perform Fourier transformations rather than taking the complex conjugate of the radiation signals. Diab, ¶ [0385]. The magnitude modules 656, 658 "perform a magnitude function wherein the magnitude on a point-by-point basis of the complex FFT points is selected for each of the respective channels." Diab, ¶ [0386]. Nothing in the cited reference discloses the claimed limitations of taking the complex conjugate and dividing the complex conjugate by the product of the magnitudes of the radiation signals as recited in claims 8 and 20.

Dependent claims 12 recites "providing a notification of the presence of venous pulsation," and dependent claim 22 recites similar language. As discussed above in relation to the independent claims 1 and 13, neither the Diab reference nor the Swedlow reference, nor a combination thereof, discloses "indicating the presence of venous pulsation" when present. As the cited references do not disclose indicating the presence of venous pulsation, they clearly do not disclose providing notification of such a presence. Accordingly, the cited references do not disclose the limitations set for in claims 12 and 22.

Again, Appellant respectfully submits that dependent claims 2-4, 6-12, 14-16, and 18-22 are allowable based at least on their dependence from allowable base claims 1 and 13. The Examiner has already indicated that dependent claims 5 and 17 contain allowable subject matter.

Final Office Action, page 4. The Examiner has not set forth a *prima facie* case of obviousness regarding these dependent claims, and recited subject matter is claimed which the cited references do not disclose. For at least the reasons set forth above, Appellant respectfully requests the Board overturn the rejection of dependent claims 2-4, 6-12, 14-16, and 18-22 under 35 U.S.C. § 103.

8. CONCLUSION

Appellant respectfully submits that all pending claims are in condition for allowance. However, if the Examiner or Board wishes to resolve any other issues by way of a telephone conference, the Examiner or Board is kindly invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

Date: February 4, 2008

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9. APPENDIX OF CLAIMS ON APPEAL

A. Listing of Claims:

1. A method of detecting the presence of mixed venous and arterial blood pulsation in tissue, comprising:

receiving first and second electromagnetic radiation signals from a blood perfused tissue portion corresponding to infrared and red wavelengths of light;

obtaining a measure of a phase difference between the first and second electromagnetic radiation signals;

comparing the measure with a threshold value to form a comparison;

detecting the presence or absence of venous pulsation using the comparison; and

indicating the presence of venous pulsation to a caregiver if venous pulsation is present.

2. The method of claim 1 comprising filtering the first and second electromagnetic radiation signals before the obtaining the measure, to pass portions of the first and second electromagnetic radiation signals having frequencies at or near the pulse rate or harmonics of the pulse rate of the blood perfused tissue.

3. The method of claim 1 wherein the obtaining a measure of a phase difference between the first and second electromagnetic radiation signals comprises obtaining a measure of a persistent phase difference between the first and second electromagnetic radiation signals.

4. The method of claim 3 wherein the obtaining a measure of a persistent phase difference comprises integrating the measure of a phase difference over a time period.

5. The method of claim 1 wherein the obtaining a measure of a phase difference comprises obtaining a measure of the openness of an ellipse on a Lissajous plot formed by comparing the first electromagnetic radiation signal against the second electromagnetic radiation signal.

6. The method of claim 1 wherein the obtaining a measure of a phase difference comprises analyzing a cross-correlation function of the first and second electromagnetic radiation signals, as a function of a delay interval between them.

7. The method of claim 1 wherein the obtaining a measure of a phase difference comprises a frequency domain analysis and subtracting the phases of the first and second electromagnetic radiation signals at a frequency.

8. The method of claim 7 wherein the subtracting the phases of the first and second electromagnetic radiation signals comprises taking the complex conjugate of the first and second electromagnetic radiation signals, and dividing the complex conjugate by the product of the magnitudes of the first and second electromagnetic radiation signals.

9. The method of claim 1 wherein the obtaining a measure of a phase difference comprises obtaining the measure of a phase difference at or near a fundamental pulse rate of the blood perfused tissue.

10. The method of claim 1 wherein the obtaining a measure of a phase difference comprises obtaining the measure of a phase difference at or near a harmonic of a pulse rate of the blood perfused tissue.

11. The method of claim 1 wherein the obtaining a measure of a phase difference comprises obtaining the measure of a phase difference at or near a fundamental or at or near a harmonic of a pulse rate of the blood perfused tissue.

12. The method of claim 1 comprising providing a notification of the presence of venous pulsation.

13. A device for detecting the presence of mixed venous and arterial blood pulsation in tissue, comprising:

means for receiving first and second electromagnetic radiation signals from a blood perfused tissue portion corresponding to infrared and red wavelengths of light;

means for obtaining a measure of a phase difference between the first and second electromagnetic radiation signals;

means for comparing the measure with a threshold value to form a comparison;

means for detecting the presence or absence of venous pulsation using the comparison; and

means for indicating the presence of venous pulsation to a caregiver when venous pulsation is present.

14. The device of claim 13 comprising a filter configured for filtering the first and second electromagnetic radiation signals before obtaining the measure, to pass portions of the first and second electromagnetic radiation signals having frequencies at or near the pulse rate or harmonics of the pulse rate of the blood perfused tissue.

15. The device of claim 13 wherein the means for obtaining a measure of a phase difference between the first and second electromagnetic radiation signals are configured for obtaining a measure of a persistent phase difference between the first and second electromagnetic radiation signals.

16. The device of claim 15 wherein the means for obtaining a measure of a persistent phase difference comprises means for integrating the measure of a phase difference over a time period.

17. The device of claim 13 wherein the means for obtaining a measure of a phase difference is configured for obtaining a measure of the openness of an ellipse on a Lissajous plot formed by comparing the first electromagnetic radiation signal against the second electromagnetic radiation signal.

18. The device of claim 13 wherein the means for obtaining a measure of a phase difference is configured for analyzing a cross-correlation function of the first and second electromagnetic radiation signals, as a function of a delay interval between them.

19. The device of claim 13 wherein the means for obtaining a measure of a phase difference is configured for a frequency domain analysis and for subtracting the phases of the first and second electromagnetic radiation signals at a frequency.

20. The device of claim 19 wherein the means for subtracting the phases of the first and second electromagnetic radiation signals is configured for taking the complex conjugate of the first and second electromagnetic radiation signals, and dividing the complex conjugate by the product of the magnitudes of the first and second electromagnetic radiation signals.

21. The device of claim 13 wherein the means for obtaining a measure of a phase difference is configured for obtaining the measure of a phase difference at or near a fundamental or at or near a harmonic of a pulse rate of the blood perfused tissue.

22. The device of claim 13 comprising means for providing a notification of the presence of venous pulsation.

10. EVIDENCE APPENDIX

None.

11. RELATED PROCEEDINGS APPENDIX

None.